

April 25, 2001

Sandra Titus  
Health Science Administrator  
Food and Drug Administration  
5630 Fishers Lane, Room 1093  
Rockville, MD 20857

Dear Ms. Titus:

On behalf of the American Academy of Allergy, Asthma, and Immunology (AAAAI) and the American College of Allergy, Asthma, and Immunology (ACAAI), we are requesting time for Bob Lanier, M.D. to present our position at the joint meeting of the Pulmonary-Allergy Drugs Advisory Committee and the Nonprescription Drugs Advisory Committee on May 11, 2001, that will address the citizen petition by Blue Cross/Blue Shield of California. Due to scheduling constraints, it would be appreciated if Dr. Lanier could present in the afternoon. The petition requests that the FDA convert fexofenadine hydrochloride, loratadine, and cetirizine hydrochloride to over-the-counter status.

Bob Lanier, M.D., will be speaking on behalf of our organizations. Dr. Lanier is the Medical Director of North Texas Institute for Clinical Trials, and is a founder and Executive Director of Medical Resources Network. Dr. Lanier also sits on the Board of Directors of the Texas Medical Association Foundation, and is the founder and Chief Operating Officer of Bob Lanier, Multimedia, a medical communications and video corporation. Attached is a copy of his CV for review.

The AAAAI and the ACAAI are strongly opposed to the non-sedating antihistamines being moved to an over-the-counter status. Both organizations believe that, if approved for the OTC market, these compounds will be less available to our patients who have had access to these valuable medications through insurance covered formularies. In addition, we believe the appropriate use of these medications needs the reinforcement of health care providers with expertise about allergic disorders. Overuse or misuse of this class of drugs for disorders in which they have no proven efficacy will increase health care costs. Conversely, underuse in appropriate allergic disorders will negatively impact the effectiveness and result in poorer outcomes. As physicians, we also fear placing these agents in an OTC status will circumvent physician evaluation, and may delay diagnosis of underlying disorders such as sinusitis, otitis, or asthma. As well, urticaria can be manifestation of a serious underlying condition which, left undiagnosed, could lead to substantial morbidity and mortality.